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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,003	04/28/2005	Helene Margaret Finney	CELL-0296	1691

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WOODCOCK WASHBURN LLP
ONE LIBERTY PLACE, 46TH FLOOR
1650 MARKET STREET
PHILADELPHIA, PA 19103

EXAMINER	
SHEN, WU CHENG WINSTON	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/533,003	FINNEY ET AL.	
	Examiner	Art Unit	
	Wu-Cheng Winston Shen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6,8-12,16-19,21,25,26,28,30 and 35-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-2,6,8-12,16-19,21,25-26,28,30,and 35-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-2, 6, 8-12, 16-19, 21, 25-26, 28, 30, and 35-37 are pending in the instant application.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-2, 6, 8-12, 16-17, 18-19, 21, 25-26, 28, 30, and 37, drawn to *a nucleic acid molecule* comprising a sequence encoding a cytoplasmic signaling molecule that comprises at least two cytoplasmic signaling sequences, wherein at least one of the cytoplasmic signaling sequences is derived from CD134 or the human inducible co-stimulator, and *a composition comprising a nucleic acid molecule* comprising a sequence encoding a cytoplasmic signaling molecule that comprises at least two cytoplasmic signaling sequences, wherein at least one of the cytoplasmic signaling sequences is derived from CD134 or the human inducible co-stimulator, in conjunction with a pharmaceutically acceptable excipient.

II. Claims 35-36, drawn to a method of treating HIV infection, asthma, cystic fibrosis, sickle cell anemia, psoriasis, multiple sclerosis, organ transplant rejection, graft-versus-host disease, diabetes, or cancer comprising administering to a patient suffering from such a disease or disorder a therapeutically effective amount of a nucleic acid molecule comprising a sequence encoding either *a cytoplasmic signaling molecule* that comprises at least two cytoplasmic signaling sequences, wherein at least one of the cytoplasmic signaling sequences is derived from CD134 or the human inducible co-stimulator, or *a chimeric receptor protein*, which comprises an extracellular ligand-binding domain, a transmembrane domain and a cytopasmic signaling domain is encoded by a nucleic acid sequences, wherein at least one of the cytoplasmic signaling sequences is derived from CD134 or the human inducible co-stimulator .

3. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. The common technical feature in the two groups, as stated in claim 1, is a cytoplasmic signaling domain/sequences derived from CD134 or human inducible co-stimulator (ICOS). However,

this common technical feature cannot be a special technical feature under PCT Rule 13.2 because the feature is shown in the prior art.

Arch et al identified TNF receptor-associated factor 2 (TRAF2) as an interacting ligand that binds the cytoplasmic signaling domain of Ox40 (also known as CD134) (Arch et al., 4-1BB and Ox40 are members of a tumor necrosis factor (TNF)-nerve growth factor receptor subfamily that bind TNF receptor-associated factors and activate nuclear factor kappaB. *Mol Cell Biol.* 18(1): 558-65, 1998).

Parry et al. teach distinct regulation of phosphatidylinositol 3-kinase, Bcl-xL, and IL-2 expression in primary human CD4 T lymphocytes by swapping human CD28 and inducible costimulatory protein (ICOS) cytoplasmic domain and analyzing the signal transduction cascades activated. (Parry et al., CD28 and inducible costimulatory protein Src homology 2 binding domains show distinct regulation of phosphatidylinositol 3-kinase, Bcl-xL, and IL-2 expression in primary human CD4 T lymphocytes. *J Immunol.* 171(1): 166-74, July 2003).

Inventions of the Groups I-II are patentably distinct each from the other because Group I are directed to drawn to a nucleic acid molecule comprising a sequence encoding a cytoplasmic signaling molecule that comprises at least two cytoplasmic signaling sequences, wherein at least one of the cytoplasmic signaling sequences is derived from CD134 or the human inducible co-stimulator, and a composition comprising a nucleic acid molecule comprising a sequence encoding a cytoplasmic signaling molecule that comprises at least two cytoplasmic signaling sequences, wherein at least one of the cytoplasmic signaling sequences is derived from CD134 or

the human inducible co-stimulator, in conjunction with a pharmaceutically acceptable excipient; Group II is directed to a method of treating HIV infection, asthma, cystic fibrosis, sickle cell anemia, psoriasis, multiple sclerosis, organ transplant rejection, graft-versus-host disease, diabetes, or cancer

Group I is distinct from Group II because the nucleic acid molecules encoding either a cytoplasmic signaling molecule or a chimeric receptor protein, or a pharmaceutical composition comprising the said nucleic acid molecule can be used in materially different processes or compositions, including investigation on the specificity of signaling transduction pathways, from that in treating diseases of Group II.

Conversely, group II is distinct from Group I because the diseases listed in Group II can be treated by materially different compositions, containing distinct reagents that include protein and/or gene therapy, from the composition of Group I.

The search of the above listed Groups I-II is distinct one from each other and not co-extensive and thereby presents search burdens on the examiner.

4. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. The following claims require election of a single species.

(1). This application contains claims directed to the following patentably distinct species: CD134 and human inducible co-stimulator (ICOS) in claim **1,** and its dependent claims 2-37, are independent or distinct because they are different species of signaling molecules required for costimulation involved in activation of resting T cells.

(2). This application contains claims directed to the following patentably distinct species: HIV infection, asthma, cystic fibrosis, sickle cell anemia, psoriasis, multiple sclerosis, organ transplant rejection, graft-versus-host disease, diabetes, and cancer in claims **35** and **36.** The species are independent or distinct because they are different diseases with different underlying causes and various methods for treatments.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims **1**, and its dependent claims 2-37, **35**, and **36** are generic.

Applicant is advised that a reply to this requirement ***must*** include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicants traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. The examiner has required restriction between product (Group I) and process (Group II, a method of using the product) claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Ram Shukla, can be reached on (571) 272-0735. The fax number for TC 1600 is (571)

273-8300. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Wu-Cheng Winston Shen

Wu-Cheng Winston Shen, Ph. D.
Patent Examiner
Art Unit 1632

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER